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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,320	02/07/2002	Russell Mumper	434-400 DIV	5127

1009 7590 04/30/2010
KING & SCHICKLI, PLLC
247 NORTH BROADWAY
LEXINGTON, KY 40507

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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04/30/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/072,320	Applicant(s) MUMPER ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,34,36-57,63-66 is/are pending in the application.
- 4a) Of the above claim(s) 47-50 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,34,36-46,51,56,57,63-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments to the claims and specification filed 02/08/2010 have been entered. Any rejection from the previous office action filed 10/09/2009 not addressed in the action below has been withdrawn.

Claim Rejections - 35 USC § 112

Claims 33-34,36-46,51,57-57 and 62-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in the previous office action filed 10/09/2009. A new rejection of claims 65-66 was necessitated by applicant's amendments to the claims. As described in the previous office action the examiner could not find support for anionic pH-sensitive film forming polymers which is a limitation of claim 65, since it depends on claim 33 and independent claim 66.

Response to Arguments

Applicant's arguments filed 02/08/2010 have been fully considered but they are not persuasive. Applicants assert that they specifically use Eudragits which are synthetic cationic and anionic polymers; therefore applicants believe they should be able to claim an anionic polymer. Thus applicants believe they have adequately described the concept of what is claimed.

The examiner disagrees. In order for any element to be excluded it must be either positively or negatively recited in the specification. Applicant's arguments revolve around their belief that it would be obvious to one of ordinary skill that when Eudragit polymers are recited it necessarily includes both the negatively and positively charged

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types of the polymer. The problem with this argument is that even though it may be obvious that Eudragit includes both negative and positive polymers it is simply not recited in the specification. A description that does not render a claimed invention obvious does not sufficiently describe that invention. But a description that renders obvious a claimed invention does not necessarily satisfy the written description requirement. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405.

Applicant further argue that they can claim a range between about 2:1 to about 4:1 since the specification described three specific data points of 2:1, 3:1 and 4:1, thus applicants believe they have support for any value between about 2:1 to 4:1.

The examiner disagrees. Applicants by showing possession of just one data point between the claimed lower and upper limits (2:1 and 4:1) does not give support for all the data points possible between about 2:1 to about 4:1. Furthermore the examiner notes that **about** 2:1 and **about** 4:1 expands the upper and lower data points to values slightly above and below these data points, however applicants only recited the specific data points and did not include the word “about” when describing these values in the specification.

. Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-34,36-37,42-46,56-57 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369), for the reasons set forth in the previous office action filed 10/09/2009. A

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new rejection of claim 65 was necessitated by applicant's amendments to the claims.

Regarding claim 65 since Suzuki discloses wax backing layers within applicants claimed scope the examiner must presume that the properties of the wax will be the same including its melting point since it is inherent that the same compound will have the same properties.

Applicant's arguments filed 02/08/2010 have been fully considered but they are not persuasive. Applicants assert that Slavtcheff fails to teach a pH sensitive mucoadhesive layer as claimed and does not recite the use of a mucoadhesive polymer.

The examiner disagrees. The pH sensitive mucoadhesive layer is defined within the claim by what it comprises, a water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film-forming polymer. As disclosed in the previous office action Slavtcheff discloses an adhesive composition containing a polymer that could be selected from anionic film forming polymers, the adhesive could further contain carbomer film former. Carbomer is claimed as a water-insoluble swellable anionic mucoadhesive polymer, thus Slavtcheff discloses the use of both of applicants claimed ingredients in the adhesive composition. Therefore the examiner considers the adhesive of Slavtcheff to be within applicants claimed scope for the mucoadhesive layer since it contains the same ingredients.

Applicants go on to assert that Suzuki expressly teaches away from the claimed invention because it excludes the pH sensitive mucoadhesive layer and a molecule of interest.

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The relevance of this assertion is unclear. Suzuki was used as a secondary reference only for its disclosure within on the use and advantages of a thin wax backing layer for adhesives used for personal use. Suzuki was not used for its disclosure on the mucoadhesive layer; the limitations for the mucoadhesive layer are met by the primary reference. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claims 33,34,36-46,51,56,57,63 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369) in view of Mantelle et al. (US 6,562,363 B1), for the reasons set forth in the previous office action filed 10/09/2009. A new rejection of claim 66 was necessitated by applicant's amendments to the claims. Claim 66 is simply a combination of the limitations of claims 33 and 39 and is therefore rejected for the reasons set forth in the previous office action.

Applicants assert that Mantelle teaches the use of Eudragit RL and RS polymers which are pH insensitive and therefore would not lead one of ordinary skill in the art to select a pH sensitive polymer as claimed.

The relevance of this assertion is unclear. Clearly Mantelle discloses the use of more than just Eudragit RL and RS, for instance the reference as just one example it discloses the use of Eudragit L100.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618